

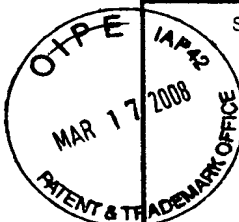
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

Application Number	10/747,686
Filing Date	December 30, 2003
First Named Inventor	STEINER, Mitchell S.
Art Unit	1618
Examiner Name	Fubara, Blessing M
Attorney Docket Number	P-2769-US9

Sheet 1 of 11

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A	4,990,538		Harris et al.	February 5, 91	
	B	5,788,964		Baral et al.	August 4, 98	
	C	5,650,425		Biegnon et al.	July 22, 97	
	D	4,696,949		Toivola et al.	Sept 29, 87	
	E	5,491,173		Toivola et al.	Feb. 13, 1996	
	F	5,571,534		Jalonen et al.	Nov. 5, 1996	
	G	5,605,700		DeGregorio et al.	Feb. 25, 1997	
	H	5,595,722		Grainger et al.	Jan. 21, 1997	
	I	5,599,844		Grainger et al.	Feb. 4, 1997	
	J	5,629,007		Audia et al.	May 13, 1997	
	K	5,635,197		Audia et al.	June 3, 1997	
	L	5,595,985		Labrie	Jan. 21, 1997	
	M	5,441,986		Thompson, et al	08-15-1995	
	N	5,852,059		Thompson, et al	12-22-1998	
	O	5,827,892		Loeser, et al	10-27-1998	
	P	5,821,254		Sporn, et al	10-13-1998	
	Q	5,859,045		Treppendahl, et al	01-12-1999	
	R	5,935,987		Treppendahl, et al	08-10-1999	
	S	5,763,415		Sukumar, Saraswati	06-1998	
	T	5,916,916		Hauser et al	06-1999	

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	U	WO	98/58634		Degregorio et al	December 30, 98		<input type="checkbox"/>
	V	EP	415 623 A2		Harris et al	March 6, 1991		<input type="checkbox"/>
	W	EP	616 529 B1		Heikkila et al	September 28, 94		<input type="checkbox"/>
	X	EP	095875		Toivola et al	Dec 7, 1983		<input type="checkbox"/>
	Y	WO	95/26720		Biegon et al	Oct 12, 1995		<input type="checkbox"/>
	Z	WO	00/08001		Huebner et al	Feb 17, 2000		<input type="checkbox"/>

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	Considered

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Sheet	2	of	11	Attorney Docket Number	P-2769-US9

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	AA	4,329,364		Neri et al.	May 11, 1982	
	AB	4,474,813		Neri et al.	Oct. 2, 1984	
	AC	6,080,877		Swindell et al	June, 2000	
	AD	6,265,448		Steiner et al	July 24, 2001	
	AE	6,410,043		Steiner et al	June 25, 2002	
	AF	6,632,447		Steiner et al	Oct 14, 2003	
	AG	6,413,533		Steiner et al	July 2, 2002	
	AH	6,413,534		Steiner et al	July 2, 2002	
	AI	6,413,535		Steiner et al	July 2, 2002	
	AJ	4,996,225		Toivola et al	Feb 26, 1991	
	AK	5,811,120		Gibson et al	Sept 22, 1998	
	AL	5,972,383		Gibson et al	Oct 26, 1999	
	AM	4,418,068		Jones	Nov 29, 1983	
	AN	5,728,707				
	AO	6,899,888		Steiner et al	05-2005	
	AP	6,569,896		Dalton et al	12-1998	

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	AQ	WO	94/12162		Warri et al	June 9, 1994		<input type="checkbox"/>
	AR	WO	99/56739		Steiner et al	November 11, 1999		<input type="checkbox"/>
	AS	WO	00/47214		Healey et al	August 17, 2000		<input type="checkbox"/>
	AT	WO	96/09046		Audia et al	March 28, 1996		<input type="checkbox"/>
	AU	EP	0 670 162		Gibson et al	Sept 6, 1995		<input type="checkbox"/>
	AV	WO	00/19998		KGK Synergize	04-13-2000		<input type="checkbox"/>
	AW	WO	97/25038		Novo Nordisk	7-17-1997		<input type="checkbox"/>
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	AY	WO	97/25037		Novo Nordisk	7-17-1997		
	AZ	WO	97/03046		Bohlmann et al	01-30-1997		
	BA	WO	98/045288		Neubauer et al	10-1998		

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				Attorney Docket Number	P-2769-US9
Sheet	3	of	11		

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		Examiner Name	Fubara, Blessing M		
Sheet	4	of	11	Attorney Docket Number	P-2769-US9

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BJ	Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.	<input type="checkbox"/>
	BK	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.	<input type="checkbox"/>
	BL	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 16H: 1-8.	<input type="checkbox"/>
	BM	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin D Analogue Ro24-553 1 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.	<input type="checkbox"/>
	BN	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.	<input type="checkbox"/>
	BO	Schneider Martin R. et al. "Nonsteroidal Antiestrogens and Partial Estrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265.	<input type="checkbox"/>
	BP	Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Steroid Biochem. Molec. Bio. Vol 64, No. 3-4, pp. 199-205, 1998.	<input type="checkbox"/>
	BQ	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.	<input type="checkbox"/>
	BR	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997	<input type="checkbox"/>
	BS	Christian Rohlf et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Kinase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc	<input type="checkbox"/>
	BT	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Res., vol. 53, no. 21, 1993, pages 5199-5207, X0002117653.	<input type="checkbox"/>
	BU	Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.	
	BV	Gingrich et al., "Pathologic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.	
	BW	Gingrich et al., "Metastatic Prostate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102.	
	BX	Gershanovich et al., "A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.	

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	December 30, 2003
				First Named Inventor	STEINER, Mitchell S.
				Art Unit	1618
				Examiner Name	Fubara, Blessing M
(use as many sheets as necessary)				Attorney Docket Number	P-2769-US9
Sheet	5	of	11		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BY	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of Toremifene in Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 13, No. 10, 1995, pages 2556-2566.	
	BZ	Pyrhonen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with Advanced Breast Cancer: a Randomized Double-blind, the 'Nordic' Phase III Study", British Journal of Cancer, 1997, 76(2), pages 270-277.	
	CA	Neubauer et al., "Endocrine and Antiproliferative Effects of Raloxifene (LY156758) in the Male Rat", The Prostate 23, 1993, pages 245-262.	
	CB	Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39, 1999, pages 305-309.	
	CC	Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	
	CD	Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40	
	CE	Hietanen T "Open Phase II Study of High-Dose Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4): 37-40.	
	CF	Black et al. "Uterine Bioassay of Tamoxifen, Trioxifene and a New Estrogen Antagonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	CG	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 17β-Estradiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357.	
	CH	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4-Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994)	
	CI	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	
	CJ	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer, pages 467-477	
	CK	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	
	CL	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toremifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66.	
	CM	Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Trials" Oncology (Huntingt) 1998 Mar; 12(3 Suppl 5): 28-31.	
	CN	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.	

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Sheet	6	of	11	Attorney Docket Number	P-2769-US9

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	CO	Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.	
	CP	Foekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5-6): 888-94.	
	CQ	Brandes LJ et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paradigm Predictive Of Tumor Growth Enhancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61.	
	CR	Miyata E et al. "Effects Of Tamoxifen, An Antiestrogen, On Rat Prostate Carcinogenesis by 3,2'-Dimethyl-4-Aminobiphenyl And Testosterone Do Not Support An Estrogen Role In Testosterone Promotion", Prostate 1997 Apr 1;31(1)9-13.	
	CS	Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate", Am J Clin Oncol 1996 Oct; 19(5):500-3.	
	CT	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate 1995 May; 26(5): 270-4.	
	CU	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.	
	CV	Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.	
	CW	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone-Refractory Prostate Cancer." Clin Cancer Res 1999 Sep; 5(9): 2366-73.	
	CX	Chang William Y et al. "Estrogen Receptor-β: Implications For The Prostate Gland" The Prostate 40:115-124 (1999)	
	CY	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-α (Er-α) And β (Er-β) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract" Steroids 63: 498-504, 1998, Elsevier Science Inc.	
	CZ	Prins Gail S. et al, "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression In The Developing And Adult Rat Prostate Lobes", Endocrinology 138: 1801-1809, 1997)	
	DA	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto-Oestrogens", British Journal Of Urology (1998). 82. 560-563.	
	DB	Awoniyi Caleb A. et al. "Neonatal Exposure To Coumestrol, A Phystoestrogen, Does Not Alter Spermatogenic Potential In Rats", Endocrine, vol. 7, no. 3, 337-341, December 1997.	
	DC	"Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", Journal of Cellular Biochemistry, Supplement 16H:140-145 (1992).	

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	DD	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 16H:138-139 (1992).	
	DE	"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-β", Endocrinology Vol. 138, No. 3, (1997).	
	DF	Kuiper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors α and β", Endocrinology Vol. 138, No. 3, 863-870 (1997).	
	DG	Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Oestrogens" Breast Cancer Research and Treatment 31: 5-9, 1994.	
	DH	Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.	
	DI	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3):291-300.	
	DJ	Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.	
	DK	Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	
	DL	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.	
	DM	Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161. 1748-1760. June 1999, p. 1748-1760.	
	DN	Fleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
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				Application Number	10/747,686
				Filing Date	December 30, 2003
				First Named Inventor	STEINER, Mitchell S.
				Art Unit	1618
				Examiner Name	Fubara, Blessing M
Sheet	8	of	11	Attorney Docket Number	P-2769-US9

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	DR	Cheng E et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71.	
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	EO	Warri Anni. M. et al "Apoptosis in Toremifene Induced Growth Inhibition of Human Breast Cancer Cells in Vivo and In Vitro" Journal of National Cancer Institute, Vol. 85, No. 17, September 1, 1993	
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				Examiner Name	Fubara, Blessing M
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	EX	Nevalainen MT et al "Hormone regulation of human prostate in organ culture" Cancer Res. 1993 Nov 1;53 (21):5199-207	
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	EZ	Nelson et al (abstract only), "Chemoprevention for prostatic intraepithelial neoplasia", Eur. Urol. 1996;30(2):269-278.	
	FA	Formulary Additions, May, 1998, "Raloxifene (Evista) 60 mg Tablets"; Pharmacy Key: a publication of the pharmacy and therapeutics committee: formulary additions: http://www2.kumc.edu/druginfo/pharmkey/pharmkey051488.html	
	FB	Frolik et al., "Time-dependent changes in biochemical bone markers and serum cholesterol in ovariectomized rats: effects of raloxifene HCl, tamoxifen, estrogen and alendronate", June 1996; Bone; 18(6):621-627.	
	FC	Sato et al., "Raloxifene: a selective estrogen receptor modulator", Journal of Bone and Mineral Metabolism 1994; 12(Suppl. 2):S9-S20.	
	FD	Fujimoto et al., "Can we prevent prostate cancer? Rationale and current status of prostate cancer chemoprevention", Urologia Internationalis (2005); 74(4): abstract.	
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	FI	Raghow, et al (2002) "Toremifene prevents prostate cancer in the transgenic adenocarcinoma of mouse prostate model." Cancer Research 1;62(5) 1370-6.	

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				Examiner Name	Fubara, Blessing M
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	FK	Black, et al (1983) "Antagonism of estrogen action with a new benzothiophene derived antiestrogen.", <i>Life Sci.</i> , 32, 1031-1036	
	FL	Knecht, et al (1985) "Estrogen dependence of luteinizing hormone receptor expression in cultured rat granulosa cells. Inhibition of granulosa cell development by the antiestrogens tamoxifen and keoxifene." <i>Endocrinology</i> , 116, 1771-1777	
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	FO	Saudek et al. (1989) "A preliminary trial of the programmable implantable medication system for insulin delivery.", <i>N. Engl. J. Med.</i> 321:574	
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	FT	Schneider, et al (1991) "Effect of zindoxifene on experimental prostatic tumors of the rat." <i>J. Cancer Res Clin Oncol.</i> 117 (1) 33-6.	
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	Examiner Blessing M. Fubara	Art Unit 1618	Page 1 of 1

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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	V	Price, New Advances in Prostate Cancer Treatment in the American Society of Clinical Oncology, 15 May 2005, abstract.
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*	C	US-5,852,059	12-1998	Thompson, David D.	514/548
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	Examiner Blessing M. Fubara	Art Unit 1618	Page 1 of 2

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Art Unit

1614

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	V	Formulary Additions, May, 1998 ("Raloxifene (Evista) 60 mg Tablets"; Pharmacy Key: A Publication of the Pharmacy and Therapeutics Committee: Formulary Additions: http://www2.kumc.edu/druginfo/pharmkey/pharmkey051498.html .)
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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Fujimoto et al. ("Can We Prevent Prostate Cancer? Rationale and Current Status of Prostate Cancer Chemoprevention"; Urologia Internationalis (2005); 74(4): abstract.)
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.